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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,280	03/04/2004	Michael R. Bowman	WYE-027	3906

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EXAMINER

LIN, JERRY

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/792,280	BOWMAN ET AL.	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,9,11 and 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,8,10,12-14 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/5/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-14 and 20, and Cationic Amino Acid Transporter in Species A, agents capable of inhibiting CAT2 in Species B, and lysine in Species C in the reply filed on July 27, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

Claims 1-4, 6, 8, 10, 12-14, and 20 are under examination.

Claims 5, 7, 9, 11, 15-19 are withdrawn as being drawn to an unelected invention.

Information Disclosure Statement

2. The International Search Report listed on the IDS filed April 15, 2005 was not considered, because the International Search Report is not a publication.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 6, 12 –14 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Ochoa et al. (US 2004/0057926).

The instant claims are drawn to a method of administering a therapeutically effective amount of an agent to a mammal with a respiratory disease where the agent inhibits the activity or expression of a component of an arginine metabolic pathway and where the component is not a nitric oxide synthase.

Regarding claims 1-4, 6, 12 –14 and 20, Ochoa et al. teach administering an therapeutically effective amount of lysine (Abstract; Pages 1-2, paragraph 0013; Page 2 ,paragraph 0016) which inhibits a component of the arginine metabolic pathway such as a cationic amino acid transporter 2 (Page 2, paragraph 0016) for treating a respiratory disease such as chronic obstructive pulmonary disease (Page 6, paragraph 0063) in a mammal such as a human (page 30, claim 2).

5. Claims 1-4, 6, 12 –14 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by MacLeod (WO/0044766).

The instant claims are drawn to a method of administering a therapeutically effective amount of an agent to a mammal with a respiratory disease where the agent inhibits the activity or expression of a component of an arginine metabolic pathway and where the component is not a nitric oxide synthase.

Regarding claims 1, 2, 13, 14, and 20, MacLeod teaches a method of administering a therapeutically effective amount of an agent to a human to inhibit the activity or expression of a component of an arginine metabolic pathway where the component is not nitric oxide synthase (paragraph bridging Pages 6-7) wherein the human has a respiratory disease (page 20).

Regarding claim 8, MacLeod teaches wherein the component is inhibited by an antisense mechanism (Page 6).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacLeod (WO/0044766) in view of Hannon (Nature (2002) volume 418, pages 244-251).

The instant claims are drawn to a method of administering a therapeutically effective amount of an agent to a mammal with a respiratory disease where the agent inhibits the activity or expression of a component of an arginine metabolic pathway and where the component is not a nitric oxide synthase, wherein the agent is siRNA.

MacLeod is applied to claims 1, 2, and 8 as above.

Regarding claim 10, Hannon teaches that siRNA may be synthesized to target and silence genes of interest (page 245; page 250).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the methods of MacLeod with Hannon to create siRNA for the purpose of inhibiting the production of CAT2. MacLeod teaches that the inhibition of CAT2 via the CAT2 mRNA is desirable to treat certain illnesses (page 6). MacLeod proposed the use of antisense oligonucleotides to inhibit the CAT2 mRNA (page 6). However, Hannon teaches that siRNA is a much more potent inhibitor of gene expression than sense or antisense RNAs (page 244, right column). Thus one of

ordinary skill in the art seeking to inhibit CAT2 mRNA would be motivated to use siRNA for the increased potency of siRNA over sense or antisense RNAs.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

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been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', with a long horizontal stroke extending to the right.

JL